

§416.41 Condition for coverage—Governing body and management.

The ASC must have a governing body, that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation and for ensuring that these policies are administered so as to provide quality health care in a safe environment. When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner. *Standard: Hospitalization.* The ASC must have an effective procedure for the immediate transfer to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC. This hospital must be a local, Medicare participating hospital or a local, non-participating hospital that meets the requirements for payment for emergency services under §482.2 of this chapter. The ASC must have a written transfer agreement with such a hospital, or all physicians performing surgery in the ASC must have admitting privileges at such a hospital.

[47 FR 34094, Aug. 5, 1982, as amended at 51 FR 22041, June 17, 1986]

§416.42 Condition for coverage—Surgical services.

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

(a) *Standard: Anesthetic risk and evaluation.* A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery.

(b) *Standard: Administration of anesthesia.* Anesthetics must be administered by only—

(1) A qualified anesthesiologist; or

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined in §410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in

which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (d) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.

(c) *Standard: Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.

(d) *Standard: State exemption.* (1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[57 FR 33899, July 31, 1992, as amended at 66 FR 56768, Nov. 13, 2001.]

§416.43 Condition for coverage—Evaluation of quality.

The ASC, with the active participation of the medical staff, must conduct an ongoing, comprehensive self-assessment of the quality of care provided, including medical necessity of procedures performed and appropriateness of care, and use findings, when appropriate, in the revision of center policies and consideration of clinical privileges.

§416.44 Condition for coverage—Environment.

The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to

protect the health and safety of patients.

(a) *Standard: Physical environment.* The ASC must provide a functional and sanitary environment for the provision of surgical services.

(1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.

(2) The ASC must have a separate recovery room and waiting area.

(3) The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.

(b) *Standard: Safety from fire.* (1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Centers of the 2000 edition of the Life Safety Code of the National Fire Protection Association, regardless of the number of patients served. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(2) In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon an ASC, but only if

the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.

(4) An ASC must be in compliance with Chapter 21.2.9.1, Emergency Lighting, beginning on March 13, 2006.

(c) *Standard: Emergency equipment.* Emergency equipment available to the operating rooms must include at least the following:

(1) Emergency call system.

(2) Oxygen.

(3) Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator.

(4) Cardiac defibrillator.

(5) Cardiac monitoring equipment.

(6) Tracheostomy set.

(7) Laryngoscopes and endotracheal tubes.

(8) Suction equipment.

(9) Emergency medical equipment and supplies specified by the medical staff.

(d) *Standard: Emergency personnel.* Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.

[47 FR 34094, Aug. 5, 1982, amended at 53 FR 11508, Apr. 7, 1988; 54 FR 4026, Jan. 27, 1989; 68 FR 1385, Jan. 10, 2003; 69 FR 18803, Apr. 9, 2004]

§ 416.45 Condition for coverage—Medical staff.

The medical staff of the ASC must be accountable to the governing body.

(a) *Standard: Membership and clinical privileges.* Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel.

(b) *Standard: Reappraisals.* Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.